A Framework and Case Study for Voluntary Children's Chemical Evaluation Program Exposure Assessment

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Sciences International, Inc.

Alexandria, Virginia

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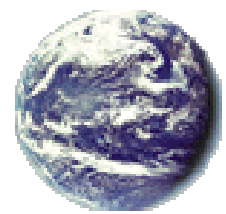
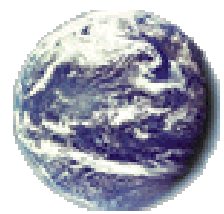


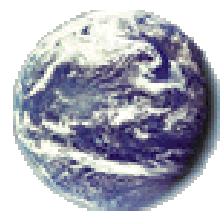
Purpose

- Develop a framework for conducting an exposure assessment for the VCCEP
- Illustrate the framework with an example exposure assessment
- Illustrate approaches to the VCCEP and the flexibility required to accommodate different chemicals and sponsors



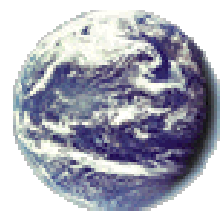
Essential Characteristics of a the Tier 1 Exposure Assessment

- Open and transparent
- Impose meaningful order on vast landscape of consideration (e.g., pathways, receptor groups, etc.)
- Preserve the integrity of the data
- Include all key factors in a way that inform exposure assessment (e.g., consideration of toxicity data)
- Focus on most significant pathways and receptor groups



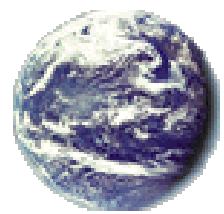
Parts of Framework

- Part 1 - Selection of exposure scenarios
  - Process by which exposure scenarios are selected for quantitative analysis
- Part 2 - Exposure assessment
  - Estimation of exposures for scenarios developed in Part 1

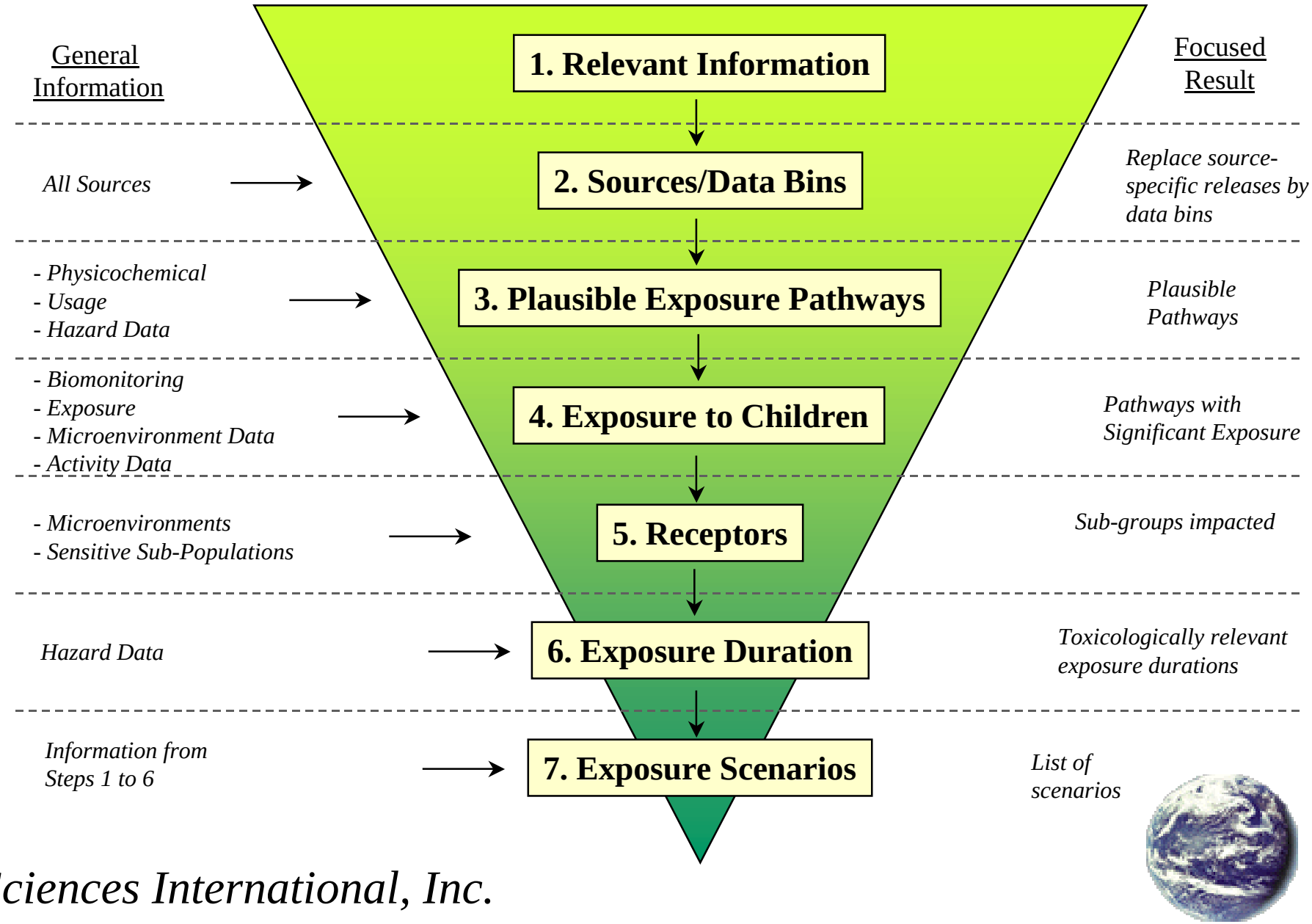


What is the Framework

- The framework describes a process to systematically organize and evaluate the universe of all possible exposure sources and pathways to efficiently and effectively derive specific exposure scenarios necessary for a screening level exposure assessment.
- The exposure scenarios are used to develop a quantitative assessment of exposures for the receptors of concern.



Part 1. Framework for Selection of Exposure Scenarios



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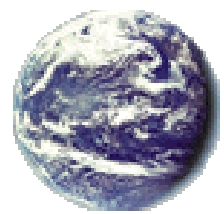
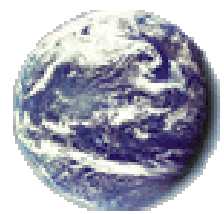
Part 1. Framework for Selection of Exposure Scenarios

- *Step 1 - Assemble relevant information*: includes production volumes; manufacturing and processing release amounts; industrial, institutional, and consumer uses of the product; outside the chain of commerce sources; disposal amounts; physicochemical properties; environmental fate properties; hazard data; and exposure data
  - Some information for chemical may not be available to sponsor
- *Step 2 - Organization of sources into data bins*: grouping of separate sources that contribute to same exposure pathway



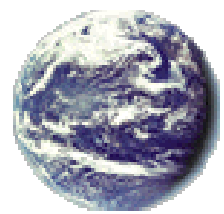
Part 1. Framework for Selection of Exposure Scenarios

- *Step 3 - Determination of plausible exposure pathways*: develop list of plausible pathways based on usage profile and physicochemical properties
- *Step 4 - Inclusion of pathways with significant exposure to children*: determination of pathways relevant to children
- *Step 5 - Consideration of receptors*: determining populations and subpopulations that may be exposed



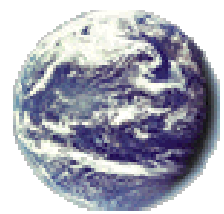
Part 1. Framework for Selection of Exposure Scenarios

- *Step 6 - Consideration of exposure durations*: consideration of appropriate exposure durations based on toxicity
- *Step 7 - Development of exposure scenarios*: final list of scenarios to consider based on steps 1 through 6

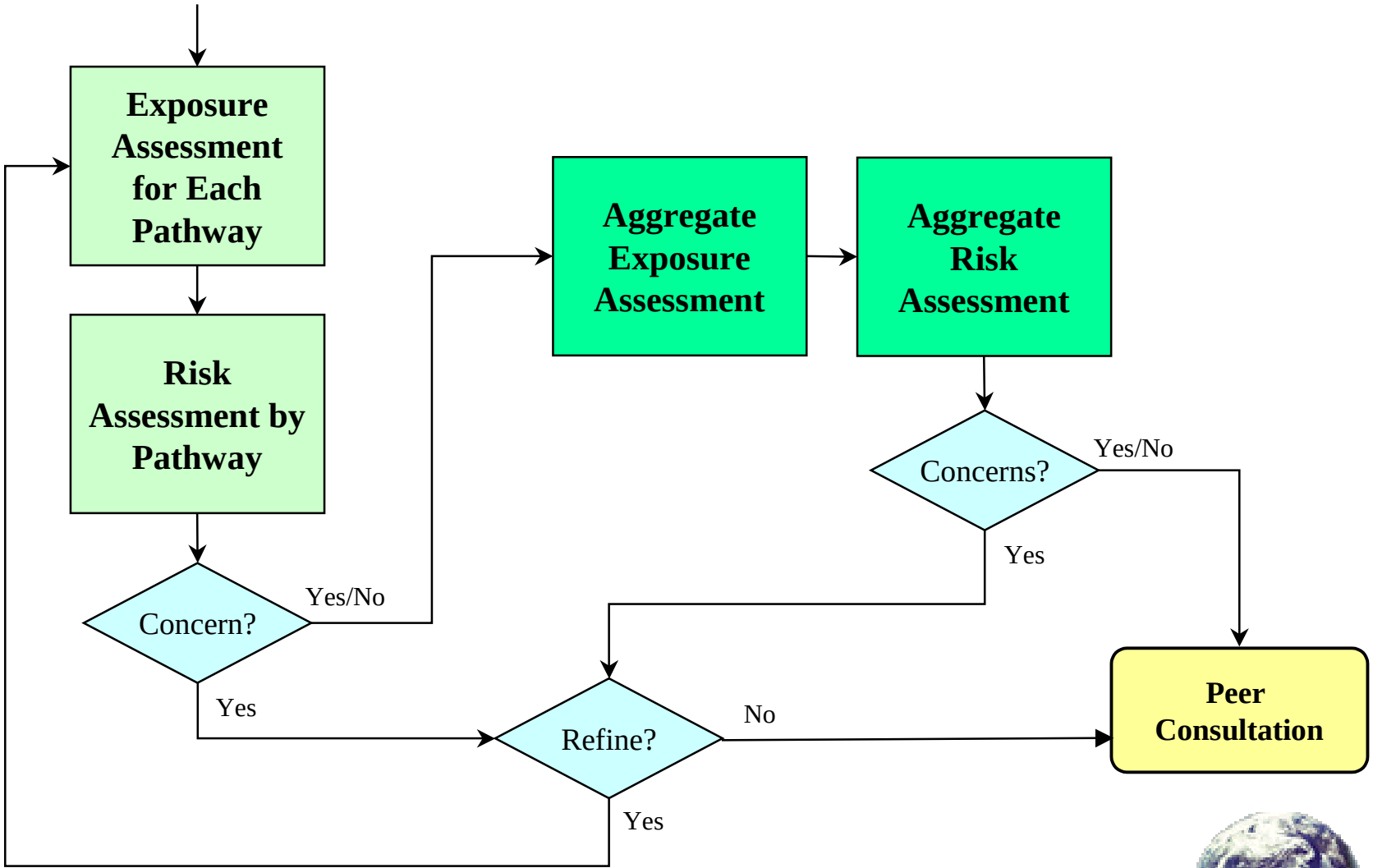


Part 2 - Exposure Assessment

- Screening-level exposure and risk assessment for exposure scenarios
- Refined exposure and risk assessment for exposure scenarios, if necessary
- Aggregate assessment
  - All exposure estimates need to be conservative, and be biased to err on the side of public safety



Refining the Assessment



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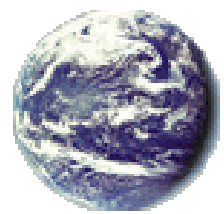
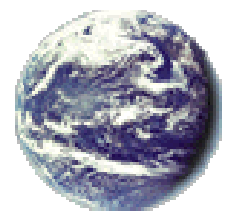
Case Study

- Based on hypothetical chemical called Seussium grinchate (SGA)
- SGA has the following uses:
  - Solvent in the manufacture of carpets
  - Component of various household cleaners
  - Solvent used in food extraction
  - Chemical intermediate



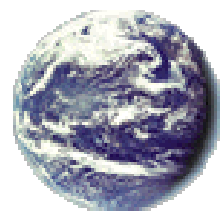
Step 1 - Assembly of Information for Exposure Assessment

- Manufacturing and usage data:
  - Produced in five manufacturing plants nationwide
  - Total production volume of 2,200 tons per year (tpy)
  - Air emissions of 88 tpy and water discharges of 2.2 tpy
  - Largest facility is operated by Whoville Industries in Whoville.
  - Also used in three plants that produce carpet, six plants that produce household cleaners, and as an intermediate for chemical processes at two facilities.



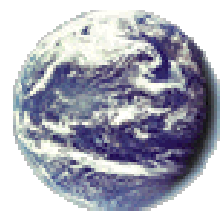
Information for Exposure Assessment (continued)

- Physicochemical properties and environmental fate
  - Slightly volatile (vapor pressure of 0.1 mmHg)
  - Low persistence in water or soil (2.5 day aerobic biodegradation half-life)
  - Low persistence in air (4 day half-life for reaction with hydroxyl radicals)



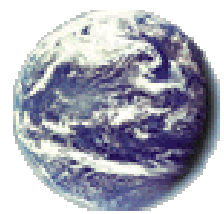
Information for Exposure Assessment (continued)

- Existing exposure and biomonitoring data
  - In EPA's TEAM study, SGA was detected in most of several thousand indoor air measurements
  - In FDA's Total Diet Study (TDS), SGA was detected in 63% of green eggs, 72% of hams, and 34% of red wine samples
  - In CDCP's NHANES study, SGA was detected in 23% of human blood samples at trace quantities



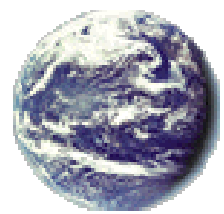
Hazard Summary

- Low acute toxicity
- Neurotoxicity by ingestion
- Respiratory irritation by inhalation
- Developmental effects
- Carcinogen by inhalation, but not ingestion
- Not an allergen, sensitizer, reproductive toxicant, or immunotoxicant



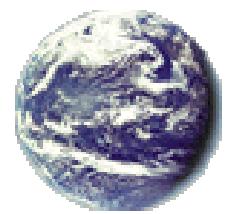
Step 2 - Organization of Sources into Data Bins

- All household cleaning products and carpets are aggregated into a data bin for the estimation of indoor air exposure
  - Therefore, these sources do not need to be considered separately



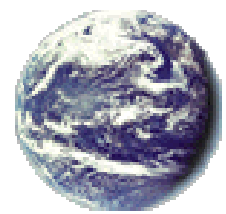
Step 3 - Determination of Plausible Exposure Pathways

- Inhalation of residential indoor air due to indoor sources
- Inhalation of ambient air due to manufacturing facilities
- Inhalation of volatilized SGA for children breathing very close to carpet surfaces
- Ingestion of food due to its detection in green eggs and ham, and in red wine
- Ingestion of breast milk by infants, due to detections in blood samples



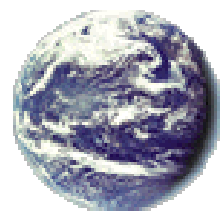
Step 3 - Determination of Plausible Exposure Pathways (continued)

- Ingestion of drinking water
- Ingestion of SGA by mouthing of toys and other objects from contact with carpet and residues from household cleaners
- Dermal contact with carpets, due to SGA use on carpets and because infants frequently play on carpet
- Dermal contact for household cleaner usage
- Occupational exposure to pregnant women, due to monitoring data in the Whoville facility and because SGA has developmental effects



Step 4 - Inclusion of Pathways with Significant Exposure to Children

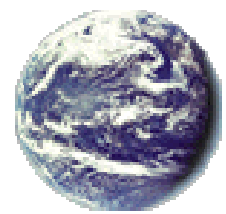
- SGA was never detected in EPA's National Drinking Water Contaminant Database (over 2,000 samples)
  - Detection limit of 0.01 µg/L
  - Wastewater removal efficiency of 99%
  - Rapid biodegradation in water
- SGA detected in green eggs, ham, and wine. But children do not generally consume wine
- Dermal contact exposure for household cleaner usage considerably less than dermal contact with carpet



Step 5 - Consideration of Receptors

Age Range	Gender	Body Weight (kg)	Inhalation Rate (m^3/day)
Infants	Both	7.1	4.5
1-2	Both	12.3	6.8
3-5	Both	17.5	8.3
6-8	Both	25.2	10
9-11	Male	35.9	14
	Female	36.6	13
12-14	Male	50.4	15
	Female	50.7	12
15-18	Male	66.5	17
	Female	66.0	12

Draft Children's Exposure Factor Handbook



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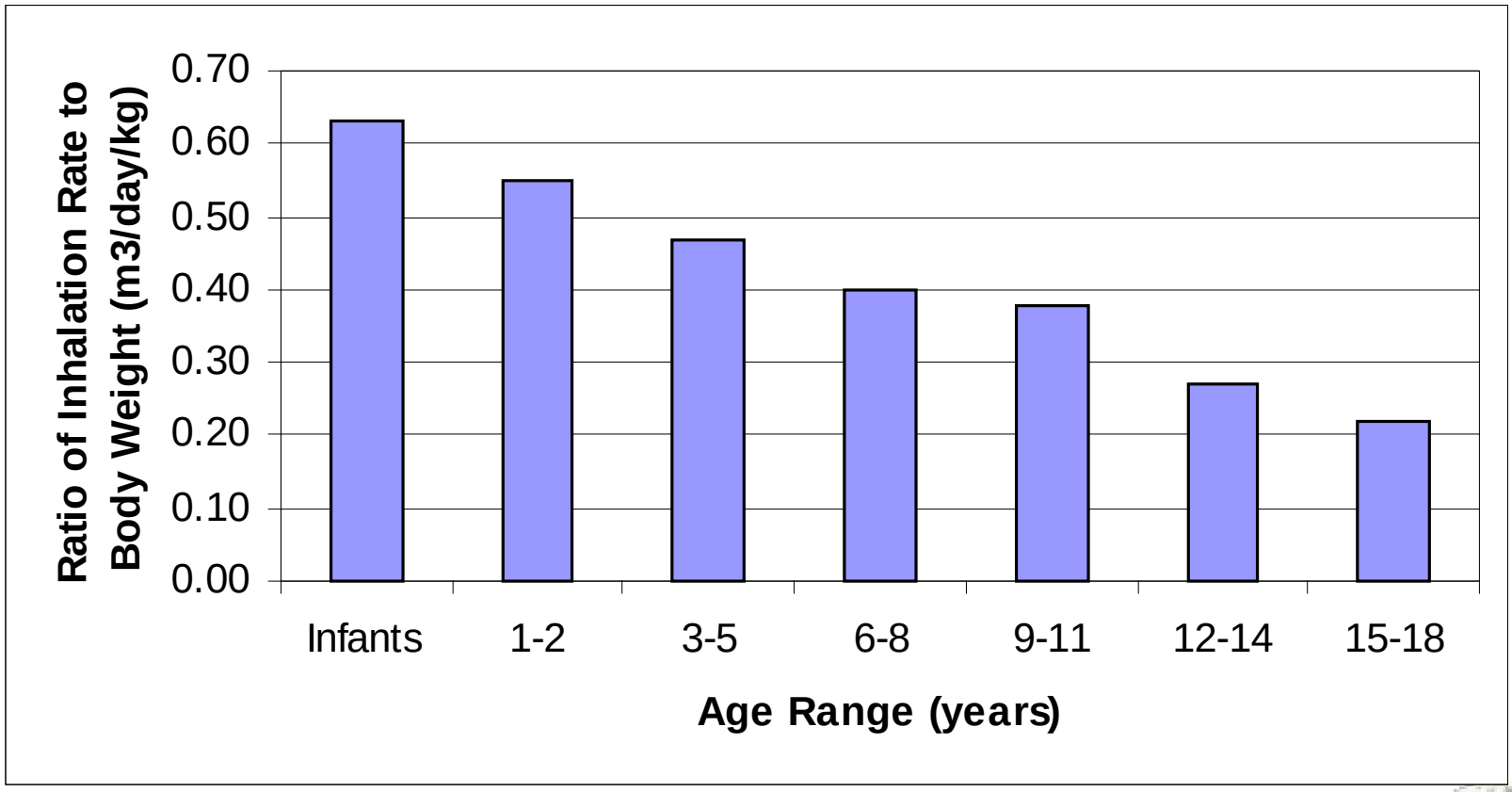
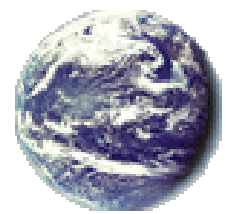
Step 5 (continued) - Ratio of Inhalation Rate to Body Weight by Age



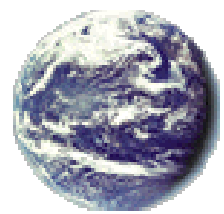
Step 5 - Consideration of Receptors: Geography (continued)

- For ambient exposure, the subpopulation of children who live near the manufacturing plants must be considered



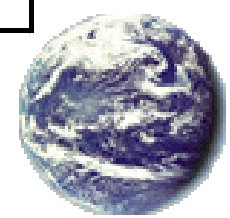
Step 6 - Consideration of Exposure Durations

- Because SGA has a very low acute toxicity, only chronic and lifetime-average exposures need to be considered
- Because SGA is only carcinogenic via inhalation and not ingestion, lifetime-average exposures will only be calculated for inhalation pathways



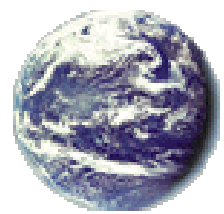
Step 7 - Development of Exposure Scenarios

Pathway	Chronic Exposure	Lifetime Exposure	Population of Concern	Significant Subpopulation
Inhalation of ambient air near plants, plus exposure to SGA from indoor sources	X	X	Children	People living near production or manufacturing plants
Ingestion of food	X		Children	
Ingestion of breast milk	X		Children	Infants
Dermal contact with carpet	X		Children	Infants
Occupational exposure	X		Pregnant women and offspring	Pregnant women working at production facilities

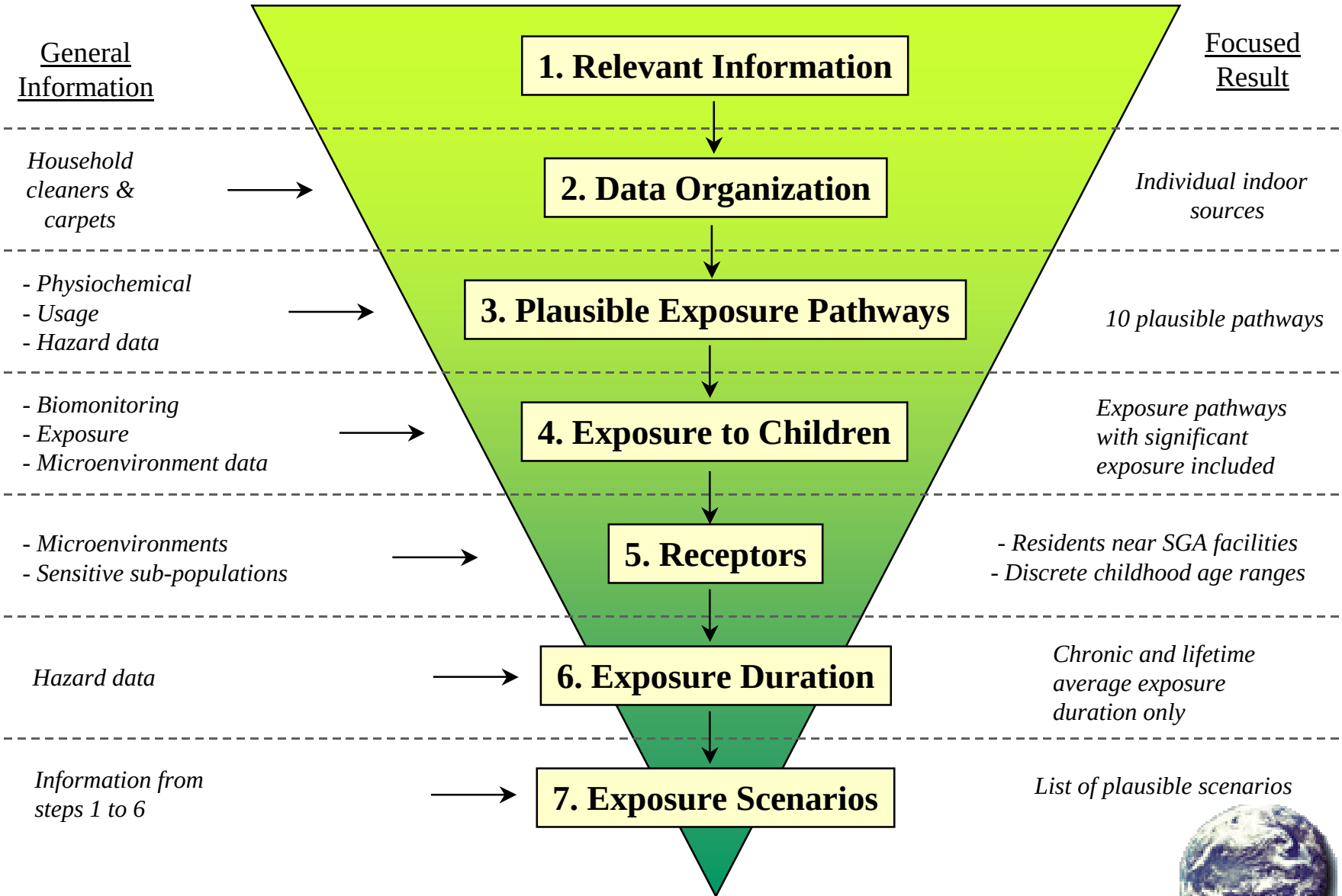


Exposure Assessment Results

- Screening-level exposure estimates err on the side of public safety:
  - Identification of highly exposed subpopulations
  - Use of upper-bound exposure estimates
  - Conservative assumptions about activity patterns (i.e., duration of exposures)
  - For food exposure, conservative assumptions about food intake



Application of Framework to Case Study



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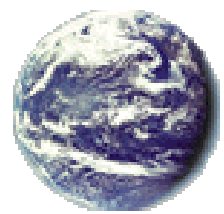
Exposure Assessment for Case Study

- Report includes a detailed exposure assessment for the five exposure scenarios
- For each scenario, a risk assessment is included to illustrate the tiered process of exposure assessment
- An aggregate assessment is included for all pathways
- For this presentation, the air inhalation pathway exposure pathway was chosen as an example illustration



Inhalation Exposure for Residents Near Production Facilities

- *Screening-Level Exposure Assessment*
  - Ambient Air
    - Dispersion modeling for the SGA manufacturing plant in Whoville, which has the highest releases and shortest distance to fenceline
    - SCREEN3 air dispersion model (very conservative and simple)
    - Emission rate and stack dimensions provided by facility
    - Maximum off-site 24-hour air concentration predicted to be 10 µg/m^3.

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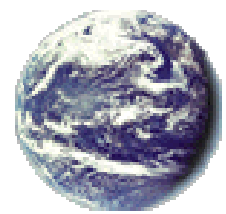
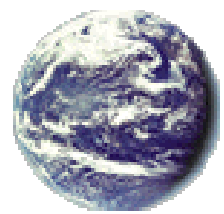


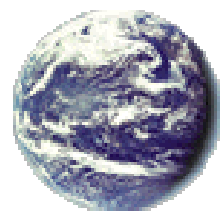
Inhalation Exposure for Residents Near Production Facilities

- *Screening-Level Exposure Assessment*
  - Indoor Air
    - SGA assumed to infiltrate into residences in a 1:1 ratio
    - Additional SGA from indoor sources. Based on TEAM study, a large measurement program of indoor air concentrations in U.S., contribution is 0.02 µg/m^3.
  - Combined Indoor and Outdoor Exposure
    - Approximately 10 µg/m^3, predominantly from outdoors

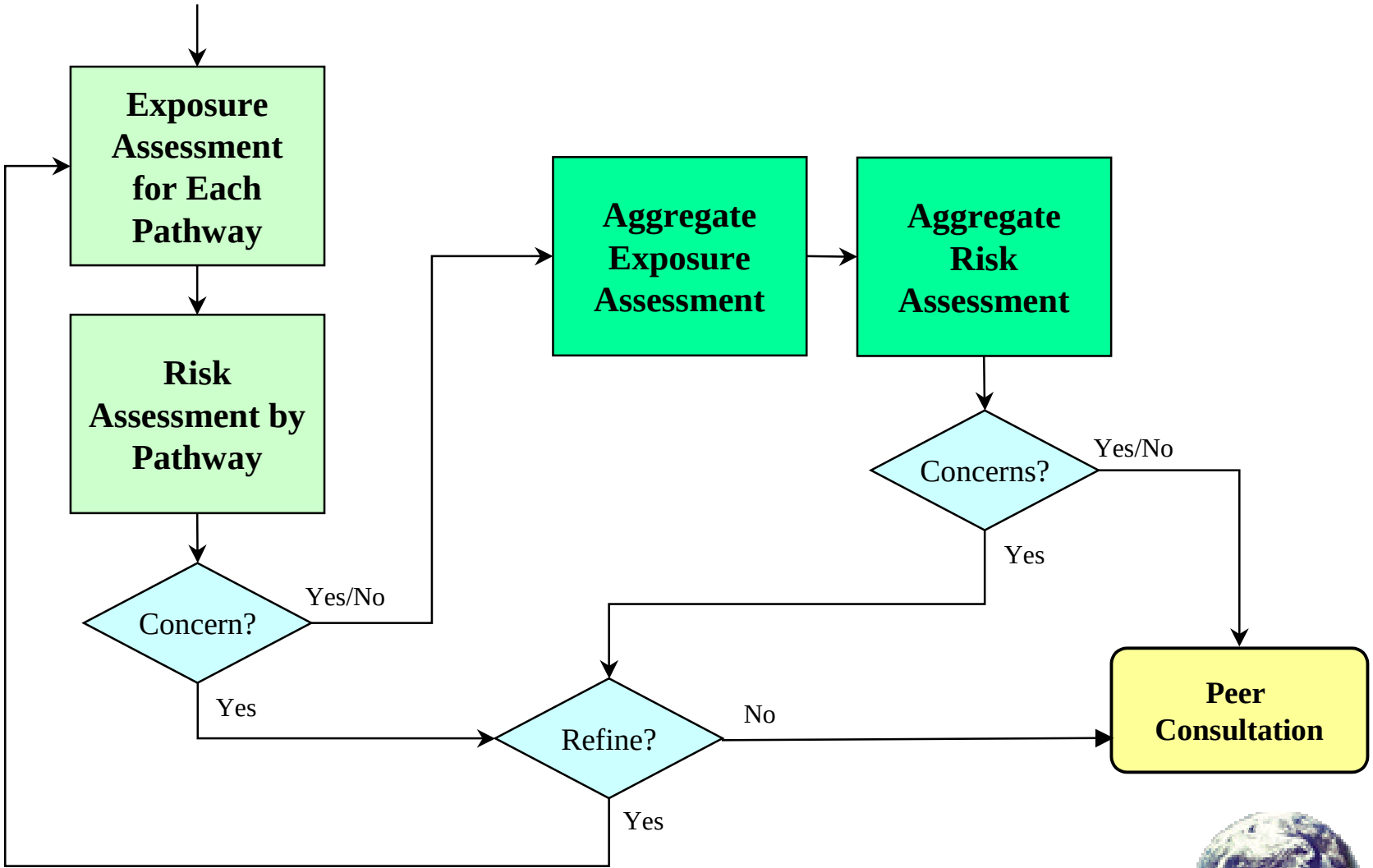


Inhalation Exposure for Residents Near Production Facilities

- *Screening Level Risk Characterization*
  - Noncancer Risk
    - With RfC of 1 mg/m^3 and exposure concentration of 10 µg/m^3, hazard index is 0.01 or well below any concern
  - Cancer Risk
    - Cancer Risk = Unit Risk ($5x10^{-6}$ per µg/m^3) * Concentration (10 µg/m^3) = $5x10^{-5}$
    - Above level of concern; therefore, a refined assessment was conducted.



Refining the Assessment



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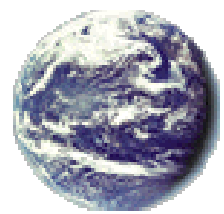
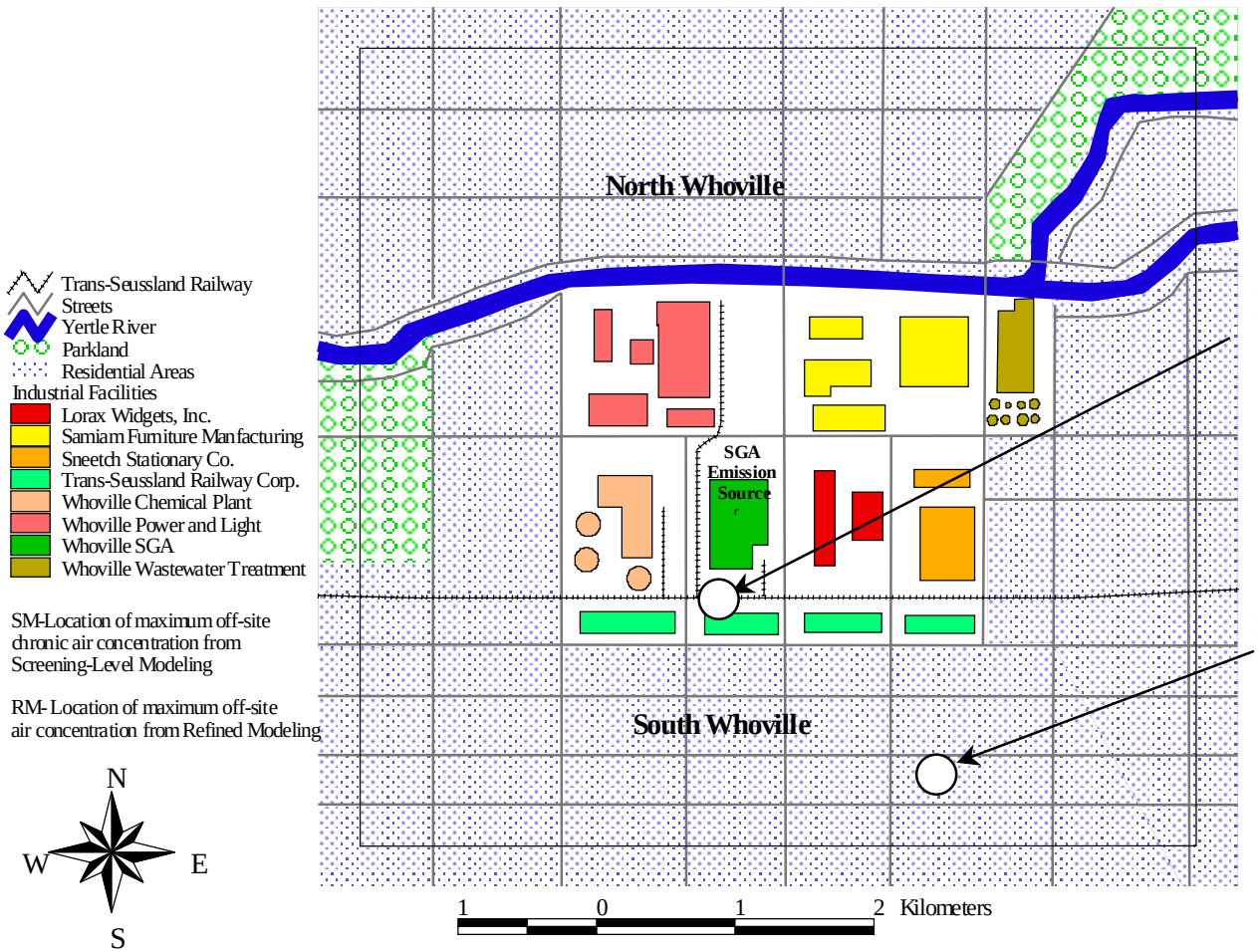
Inhalation Exposure for Residents Near Production Facilities

- *Refined Exposure Assessment*
  - Additional resources were expended to collect more data and use a more accurate and sophisticated model
    - ISCST3, a more sophisticated dispersion model is used
    - Five years of meteorological data from nearest National Weather Service station
    - Survey of land use around Whoville facility conducted; locations of residences and schools determined
    - Assumptions about time spent indoors and outdoors



Map of Whoville Facility



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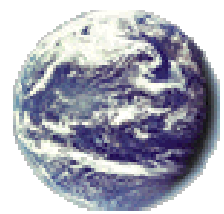
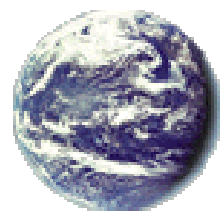
Inhalation Exposure for Residents Near Production Facilities

- *Refined Exposure Assessment*
  - The more accurate and realistic exposure assessment was 0.04 µg/m^3 compared to 10 µg/m^3 from screening level assessment.
  - Total exposure (indoor + outdoor) is 0.06 µg/m^3
- *Refined Risk Characterization*
  - Cancer risk is well below 10^{-5}

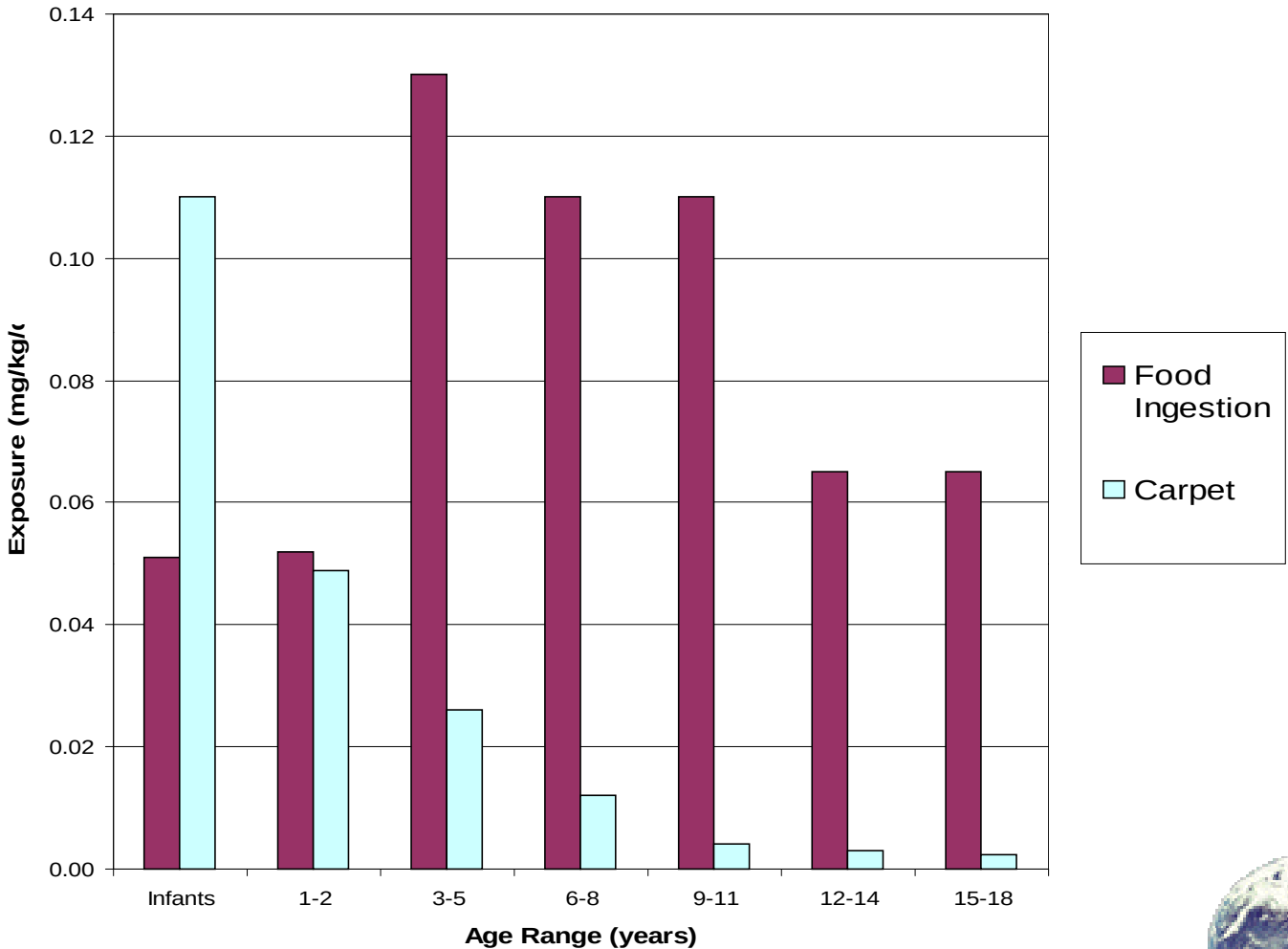


Aggregate Assessment

- *Exposure Assessment*
  - Considered combined exposure from inhalation (assumed 100 percent absorption), ingestion of food, ingestion of breast milk, and dermal contact with carpet
  - Exposure ranges from 0.067 (15 to 18 year olds) to 0.16 mg/kg/day (infants)
  - Dermal contact with carpet largest contributor for younger children, and food ingestion for older children
- *Risk Characterization*
  - Exposures below RfD, no concerns



Aggregate Exposure by Pathway: Dermal and Food
(Inhalation and ingestion of breast milk are negligible)



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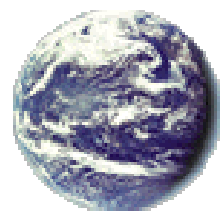
Summary of Methodologies and Lessons in Case Study

- Development of methodology to identify potential exposure pathways for a chemical
- Focus on pathways of primary concern
- Simple “check-the-box” methods are insufficient
- Development of methodologies to refine screening level assessment, if necessary (even if its not required)
  - Process may end at screening level or continue to a more refined level



Summary of Methodologies and Lessons in Case Study

- Need to consider hazard data when doing exposure assessment
- End result must be completely open, transparent, and accountable
- Flexibility required to accommodate different chemicals and sponsors